PTO/SB/08a (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Application Number		10595971	
INFORMATION DIGGL COURT	Filing Date		2006-05-23	
INFORMATION DISCLOSURE	First Named Inventor Hump		phrey	
STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Art Unit		NA	
(not for submission under or or it masy	Examiner Name	Not A	ssigned	
	Attorney Docket Numb	er	80-06	

				U.S.I	PATENTS	Remove
Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5714576		1998-02-03	Hruby et al.	
	2	5683981		1997-11-04	Hruby et al.	
	3	5674839		1997-10-07	Hruby et al.	
	4	5049547		1991-09-07	Hruby et al.	
	5	4918055		1990-04-17	Hruby et al.	
	6	4866038		1989-09-12	Hruby et al.	
	7	4485039		1989-11-27	Hruby et al.	
	8	4457864		1984-07-03	Hruby et al.	
If you wis	n to ac	dd additional U.S. Paten	t citatio	n information pl	ease click the Add button.	Add

Application Number		10595971		
Filing Date		2006-05-23		
First Named Inventor	Hum	phrey		
Art Unit		NA		
Examiner Name	Not A	ssigned		
Attorney Docket Number		80-06		

			U.S.P	ATENT	APPLI	CATION PUBI	LICATIONS		Remove	
Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publica Date	tion	Name of Pate of cited Docu	entee or Applicant ment	Releva	s,Columns,Lines where ant Passages or Releves Appear	
	1									
If you wish to add additional U.S. Published Application citation information please click the Add button. Add										
				FOREIC	N PAT	ENT DOCUM	ENTS		Remove	
Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ²		Kind Code ⁴	Publication Date	Name of Patentee Applicant of cited Document	e or	Pages,Columns,Lines where Relevant Passages or Relevan Figures Appear	T5
	1	05048967	WO			2005-06-02	Humphrey			
	2	03072072	WO			2003-09-04	Dorr et al.			
	3	87004623	WO			1987-08-13	Hruby et al.			
	4	618733	AU			1992-01-09	Hruby et al.			
	5	597630	AU			1990-06-07	Hruby et al.			
If you wis	h to ac	dd additional Foreign P	atent Do	cument	citation	information pl	ease click the Add	button	Add	
			NON	-PATEN	NT LITE	RATURE DO	CUMENTS		Remove	
Examiner Initials*	Cite No	Include name of the a (book, magazine, jour publisher, city and/or	nal, seria	al, symp	osium,	catalog, etc), o				T5

Application Number		10595971		
Filing Date		2006-05-23		
First Named Inventor	Hump	phrey		
Art Unit		NA		
Examiner Name Not A		ssigned		
Attorney Docket Number		80-06		

1	Abdel-Malek et al. (Feb. 1995) "Mitogenic and Melanogenic Stimulation of Normal Human Melanocytes by Melanotropic Peptides," Proc. Natl. Acad. Sci. USA 92(5):1789-1793	
2	Abdel-Malek et al. (Oct. 1999) "The Melanocortin-1 Receptor and Human Pigmentation," Ann. N.Y. Acad. Sci. 885:117-133	
3	Abel-Malek et al. (2000) "The Melanocortin-1 Receptor is a Key Regulator of Human Cutaneous Pigmentation," Pigment Cell Res. 13(Sup. 8):156-162	
4	Bastiaens et al. (2001) "Melanocortin-1 Receptor Gene Variants Determine the Risk of Nonmelanoma Skin Cancer Independently of Fair Skin and Red Hair," Am. J. Hum. Genet. 68(4):884-894	
5	Box et al. (1997) "Characterization of Melanocyte Stimulating Hormone Receptor Variant Alleles in Twins with Red Hair," Hum. Mol. Genet. 6(11):1891-1897	
6	De Luca et al. (1993) "Alpha Melanocyte Stimulating Hormone (Alpha MSH) Stimulates Normal Human Melanocyte Growth by Binding to High-Affinity Receptors," J. Cell. Sci. 105(4):1079-1084	
7	Dorr et al. (2000) "Increased Eumelanin Expression and Tanning is Induced by a Superpotent Melanotropin [Nle4-D-Phe7]-Alpha-MSH in Humans," Photochem. Photobiol. 72(4):526-532	
8	Dwyer et al. (1998) "The Use of Spectrophotometry to Estimate Melanin Density in Caucasions," Cancer Epidermiol. Biomarkers Prev. 7(3):203-206	
9	Dwyer et al. (2002) "Cutaneous Melanin Density of Caucasians Measured by Spectrophotometry and Risk of Malignant Melanoma Basal Cell Carcinoma, and Squamous Cell Carcinoma of the Skin," Am. J. Epidemiol. 155 (7):614-621	
10	Fitzpatrick, T.B. (1988) "The Validity and Practicality of Sun-Reactive Skin Types I Through VI," Arch. Dermatol. 124 (6):869-871	
11	Frandberg et al. (1998) "Human Pigmentation Phenotype: A Point Mutation Generates Nonfunctional MSH Receptor," Biochem. Biophys. Res. Commun. 245(2):490-492	

Application Number		10595971		
Filing Date		2006-05-23		
First Named Inventor	Hump	phrey		
Art Unit		NA		
Examiner Name	Not A	ssigned		
Attorney Docket Number		80-06		

12	Healy et al. (2001) "Functional Variation of MC1R Alleles from Red-Haired Individuals," Hum. Mol. Genet. 10 (21):2397-2402	
13	Hunt et al. (1994) "Alpha-Melanocyte Stimulating Hormone and Its Analogue Nle4DPhe7 Alpha-MSH Affect Morphology, Tyrosinase Activity and Melanogenesis in Cultured Human Melanocytes," J. Cell. Sci. 107(1):205-211	
14	Hunt et al. (1995) "Nle4DPhe7 Alpha-Melanocyte-Stimulating Hormone Increases the Eumelanin:Phaeomelanin Ratio in Cultured Human Melanocytes," J. Invest. Dermatol. 104(1):83-85	
15	Jimenez-Cervantes et al. (2001) "Thr40 and Met122 are New Partial Loss-of-Function Natural Mutations of the Human Melanocortin 1 Receptor," FEBS Lett. 508(1):44-48	
16	John et al. (2002) "Four Novel Variants in MC1R in Red-Haired South African Individuals of European Descent: S83P, Y152X, A171D, P256S," Hum. Mutat. 19(4):461-462	
17	Kadekaro et al. (Jun. 2003) "Significance of the Malenocortin 1 Receptor in Regulating Human Melanocyte Pigmentation, Proliferation, and Survival," Ann. N.Y. Acad. Sci. 994:359-365	
18	Kennedy et al. (2001) "Melanocortin 1 Receptor (MC1R) Gene Variants are Associated with and Increased Risk for Cutaneous Melanoma Which is Largely Independent of Skin Type and Hair Color," J. Invest Dermatol. 117(2):294-300	
19	Levine et al. (1991) "Induction of Skin Tanning by Subcutaneous Administration of a Potent Synthetic Melanotropin," JAMA 266(19):2730-2736	
20	Menon et al. (1983) "A Comparative Study of the Physical and Chemical Properties of Melanins Isolated from Human Black and Red Hair," J. Invest. Dermatol. 80(3):202-206	
21	Menon et al. (1983) "Effects of Ultraviolet-Visible Irradiation in the Presence of Melanin Isolated from Human Black or Red Hair Upon Ehrlich Ascites Carcinoma Cells," Cancer Res. 43(7):3165-3169	
22	Palmer et al. (2000) "Melanocortin-1 Receptor Polymorphisms and Risk of Melanoma: Is the Association Explained Solely by Pigmentation Phenotype," Am. J. Hum. Genet. 66(1):176-186	

Application Number		10595971		
Filing Date		2006-05-23		
First Named Inventor	Hump	phrey		
Art Unit		NA		
Examiner Name	Not A	ssigned		
Attorney Docket Number		80-06		

Standard ST. 4 Kind of docu	¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.								
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.									
Examiner S	Examiner Signature Date Considered								
			EXAMINER SIGNATURE						
If you wish	to ad	ld add	litional non-patent literature document citation information please click the Add butto	n Add					
	30	Valverde et al. (1996) "The Asp84Glu Variant of the Melanocortin 1 Receptor (MC1R) is Associated with Melanoma," Hum. Mol. Genet. 5(10):1663-1666							
	29		n et al. (2003) "Genetic Association and Cellular Function of MC1R Variant Alleles in Human I Acad Sci. 994:348-358	Pigmentation," Ann.					
	28	Sturm et al. (Oct. 2002) "Skin Colour and Skin Cancer – MC1R, The Genetic Link," Melanoma Res. 12(5):406-416							
	27	Smith et al. (1998) "Melanocortin 1 Receptor Variants in an Irish Population," J. Invest. Dermatol. 111(1):119-122							
	26		Scott et al. (2002) "Human Melanocortin 1 Receptor Variants, Receptor Function and Melanocyte Response to UV Radiation," J. Cell. Sci. 115(11):2349-2355						
	25		Schioth et al. (1999) "Loss of Function Mutations of the Human Melanocortin 1 Receptor are Common and are Associated with Red Hair." Biochem. Biophys. Res. Commun. 260(2):488-491						
	24		Sawyer et al. (Oct. 1980) "4-Norleucine, 7-D-Phenylalanine-Aplpha-Melanocyte-Stimulating Hormone: A Highly Potent Alpha-Melanotropin with Ultralong Biological Activity," Proc. Natl. Acad. Sci. USA 77(10):5754-5758						
	23		chez et al. (2002) "Loss-of-Function Variants of the Human Melanocortin-1 Receptor Gene in I ne Structural Determinants of Receptor Function," Eur. J. Biochem. 269(24):6133-6141	Melanoma Cells					

(Not for submission under 37 CFR 1.99)

Application Number		10595971		
Filing Date		2006-05-23		
First Named Inventor	Hump	phrey		
Art Unit		NA		
Examiner Name Not A		ssigned		
Attorney Docket Number		80-06		

		CERTIFICATION	STATEMENT				
Plea	ase see 37 CFR 1	.97 and 1.98 to make the appropriate selecti	on(s):				
	That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).						
OR							
	foreign patent of after making rea any individual de	information contained in the information difice in a counterpart foreign application, an sonable inquiry, no item of information contestignated in 37 CFR 1.56(c) more than the 37 CFR 1.97(e)(2).	id, to the knowledge of tha ained in the information di	e person signing the certification sclosure statement was known to			
	See attached ce	rtification statement.					
	Fee set forth in 3	7 CFR 1.17 (p) has been submitted herewith	١.				
√	None						
		SIGNA					
	ignature of the ap n of the signature.	plicant or representative is required in accord	dance with CFR 1.33, 10.1	18. Please see CFR 1.4(d) for the			
Sigr	nature	/ellenwinner/	Date (YYYY-MM-DD)	2006-08-29			
Nan	Name/Print Ellen P. Winner Registration Number 28547						
pub 1.14	lic which is to file o	rmation is required by 37 CFR 1.97 and 1.98 (and by the USPTO to process) an application is estimated to take 1 hour to complete, inclued USPTO. Time will vary depending upon the	on. Confidentiality is gover iding gathering, preparing	rned by 35 U.S.C. 122 and 37 CFR and submitting the completed			

require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria**,

VA 22313-1450.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

- 1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.
- 2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
- 3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
- 4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
- 5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
- 6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
- 7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
- 8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
 - 9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.